



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/171,916	02/16/99	NAIR	S 1579-312

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EXAMINER

GUZO, D

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/171,916

Applicant(s)

NAIR ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 25-42 and 44-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51-59 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-9, 13, 18, 19, 25, 28, 30, 33, 34, 36-38, 41, 42, 45, 46, 48 and 49 is/are rejected.
- 7) ☒ Claim(s) 3-5, 10-12, 14-17, 26, 27, 29, 31, 32, 35, 39, 40, 44, 47 and 50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 120 or 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1, 2, 6-9, 13, 18, 19, 25, 28, 30 and 45-46 are rejected under 35

U.S.C. 102(a) as being anticipated by Boczkowski et al.

Both applicants and Boczkowski et al. (J. Exp. Med., August 1996, Vol. 184, pp. 465-472, see whole article, particularly the "Materials and Methods" section on pp. 466-468) recite the same method for producing an RNA-loaded APC by introducing into a dendritic cell (DC) tumor-derived RNA (polyA+ and total RNA which can be from melanoma cells) which is fractionated with respect to a non-RNA component of the tumor extract, an RNA loaded APC produced by the above method, a method for producing a CTL that is cytotoxic for a cell which presents a tumor antigen, said method comprising contacting a T lymphocyte with an RNA loaded APC and culturing the T lymphocyte under conditions conducive to CTL proliferation and CTLs produced by this method as well as detecting sensitization (in a cytotoxicity assay) of the contacted CTLs as an indication of the induction of a CTL response.. Therefore, Boczkowski et al. teach the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 42 is rejected under 35 U.S.C. 102(b) as being anticipated by Riddell et al.

Both applicants and Riddell et al. (J. Immunol., 1991, Vol. 146, No. 8, pp. 2795-2804, see whole article, particularly the "Materials and Methods" section on pp. 2796-97) recite isolated CTLs which are cytotoxic for a cell which presents a pathogen antigen. Applicants claim the CTL in a product by process context and since there is no evidence that the CTL produced by Riddell et al. would be patentably distinct or non-obvious over a CTL produced by the instant process, the above 102 rejection is warranted (See MPEP 2113).

Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Riddell et al.

Both applicants and Riddell et al. (U.S. patent 5,827,642, see whole document, particularly columns 6-8) recite isolated CTLs which are cytotoxic for cells presenting tumor antigens. The claimed CTLs are recited in a product by process context and given the absence of evidence that the CTLs produced by the method of Riddell et al. are patentably distinct or non-obvious over the instantly claimed CTLs, a 102 rejection is warranted.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 33, 34, 36, 37, 38, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boczkowski et al. in view of Rouse et al.

Applicants claim a method for producing an RNA-loaded APC that presents on its surface a pathogen antigenic epitope encoded by the RNA wherein the epitope induces T cell proliferation wherein the method comprises introducing into a APC RNA (i.e. polyA+) of a pathogen (which can be a virus) consisting essentially of RNA encoding a pathogen antigen that induces T cell proliferation and an immune response in the host. Applicants also claim a method for producing a CTL that is cytotoxic for a cell which presents a pathogen antigen wherein the method comprises

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contacting a T lymphocyte with a APC produced as above and culturing the T lymphocyte under conditions conducive to CTL proliferation. Applicants also claim an isolated CTL produced by the claimed method.

Boczkowski et al. is cited as in the above 35 USC 102(a) rejection. Boczkowski et al. does not teach a method for generating an RNA-loaded APC which presents a pathogen antigenic epitope encoded by the RNA wherein said epitope induces T cell proliferation as well as a method for generating CTLs cytotoxic for cells presenting a pathogen antigen as well as CTLs produced by the method.

Rouse et al. (J. Virol., 1994, Vol. 68, No. 9, pp. 5685-5689, see whole article, particularly the Abstract and the "Materials and Methods" section) recites the generation of APCs (by transfecting the APCs with DNA encoding a viral antigen) which express an antigen from a HSV virion and the use of said APCs to stimulate generation of CTLs specific for cells presenting the viral antigen.

Boczkowski et al. teaches essentially the same methods of generating APCs and CTLs with the exception that RNA is introduced into the APCs rather than DNA encoding the antigen of choice. The ordinary skilled artisan, given the teachings of Boczkowski et al. on the generation of RNA loaded APCs which can induce generation of CTLs cytotoxic for the tumor antigen expressing cells would have been motivated to generate RNA loaded APCs which express a viral antigen(s) because Rouse et al. teaches that APCs which express antigens for pathogens such as HSV can be

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generated by introducing DNA encoding the antigen into APCs and that CTLs specific for cells expressing the viral antigen can be generated. Since the DNA plasmids encoding the HSV antigens are transcribed into mRNA during the expression process, the ordinary skilled artisan would have had a reasonable expectation of success in merely substituting RNA encoding the antigen (as recited by Boczkowski et al.) rather than the DNA recited by Rouse et al. It would have been obvious for the ordinary skilled artisan to combine the teachings of Rouse et al. with Boczkowski et al. because Rouse et al. teaches that APCs expressing viral antigens are effective simulators of CTLs and merely substituting RNA encoding the viral antigen rather than DNA saves a step in the antigen expression process. Given the teachings of the cite prior art and the level of skill of the ordinary skilled artisan at the time the instant invention was made, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 48-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 48 is vague in the recitation of the term “(“trafficking sequence”)” as this term appears to be redundant given the preceding language of the claim. Redrafting the claim to insert the term --trafficking sequence-- after the term “comprises a” in line 2 and deleting the term “(trafficking sequence”)” in line 4 would be remedial.

Claim 49 is vague in that there is no antecedent basis for the term “said trafficking sequence” in claim 1.

7. Claim 28 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 28 recites that the RNA can be isolated from any cell; however, claim 1 recites that the RNA is isolated from a tumor. Therefore, Claim 28 is broader with regard to the source of the RNA and does not further limit the subject matter of the claim from which it depends.

The Terminal Disclaimer filed 8/21/01 is acceptable.

Any rejections not repeated in this Office Action are withdrawn.

Claims 51-59 are allowed.

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Claims 3-5, 10-12, 14-17, 26-27, 29, 31-32, 35, 39-40, 44, 47 and 50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Responses can be faxed directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3291.

David Guzo
November 5, 2001

DAVID GUZO
PRIMARY EXAMINER
